

IN THE CLAIMS:

Please amend claim 49 and add new claims 94 - 100 as reflected below. A complete listing of all claims and their status follows:

Claims 1-32 (cancelled)

33. (previously presented) A method of introducing a fluent material into a disc space comprising the steps of:

creating an opening through the annulus fibrosis of a spinal disc in communication with the intradiscal space;

sealing said opening; and

introducing said fluent material through said seal directly into said intradiscal space.

34. (previously presented) The method of claim 33, wherein said fluent material is introduced through a tube placed through said seal.

35. (previously presented) The method of claim 34, wherein said seal is disposed within said opening.

36. (previously presented) The method of claim 35, wherein said seal is disposed on said tube.

37. (previously presented) The method of claim 34, further including the step of placing a cannula having a lumen therethrough into said opening and inserting said tube through said lumen.

38. (previously presented) The method of claim 37, wherein said seal is disposed within said lumen.

39. (previously presented) The method of claim 38, wherein said cannula is configured to distract two vertebrae on opposite surfaces of said disc upon placement of said cannula into said opening.

40. (previously presented) The method of claim 33, wherein the step of introducing fluent material comprises introducing the material under pressure.

41. (previously presented) The method of claim 40, wherein the fluent material is a curable biomaterial introduced into said intradiscal space in liquid form.

42. (previously presented) The method of claim 41, wherein said pressure is substantially maintained until the biomaterial is cured.

43. (previously presented) The method of claim 40, further comprising the step of providing a vent in communication with said intradiscal space and introducing the biomaterial into said intradiscal space until the biomaterial seeps from said vent.

44. (previously presented) The method of claim 43, further comprising the step of closing said vent upon seepage of biomaterial from the vent to thereby increase the pressure of biomaterial in the disc space.

45. (previously presented) A method of restoring disc height between two opposing vertebral bodies of the spine, comprising the steps of:

creating an opening through the disc annulus fibrosis in communication with the intradiscal space;

distracting the vertebral bodies apart to a selected spacing approximating natural disc height;

sealably introducing a curable biomaterial through said opening directly into the intradiscal space until the intradiscal space is substantially filled; and

maintaining the vertebral bodies in distraction until the biomaterial is substantially cured *in situ*.

46. (previously presented) The method of claim 45, further including the step of removing at least a portion of the nucleus pulposus of the disc.

47. (previously presented) The method of claim 45, further including the step of removing substantially all of the nucleus pulposus of the disc.

48. (previously presented) The method of claim 45, wherein the step of sealably introducing the curable biomaterial comprises introducing the biomaterial under pressure.

49. (currently amended) The method of claim ~~45~~ 48, wherein the step of sealably introducing the biomaterial into the intradiscal space includes placing a seal adjacent said opening and causing fluent material to flow through said seal.

50. (previously presented) The method of claim 49, wherein pressure is substantially maintained until the biomaterial is cured.

51. (previously presented) The method of claim 45, wherein the distraction step is performed prior to the step of introducing the curable biomaterial.

52. (previously presented) The method of claim 45, wherein the distraction step is performed by a separate distractor.

53. (previously presented) The method of claim 52, wherein said distractor is a cannulated distractor having a lumen in communication with the intradiscal space.

54. (previously presented) A device for sealably introducing fluent material directly into the disc space through an opening formed through the annulus fibrosis of said disc, comprising:

a seal for cooperatively engaging said annulus fibrosis adjacent said opening for sealing said opening; and

a tube having a passageway for the flow of fluent material therethrough, said tube being configured for cooperative sealed engagement through said seal.

55. (previously presented) The device of claim 54, wherein said tube is defined by a cannula having an interior lumen extending therethrough.

56. (previously presented) The device of claim 55, wherein said seal is disposed on the said cannula.

57. (previously presented) The device of claim 56, wherein said seal is integral with at least a portion of said cannula.

58. (previously presented) The device of claim 56, wherein said seal is a separate component disposed on said cannula.

59. (previously presented) The device of claim 58, wherein said seal comprises a plurality of elastomeric rings.

60. (previously presented) The device of claim 59, wherein said cannula is configured to distract vertebrae adjacent to the disc space.

61. (previously presented) The device of claim 54, wherein said seal is configured for disposition in said opening.

62. (previously presented) The device of claim 61, wherein said seal includes a cannula separate from said tube, said cannula having an interior lumen through which said tube extends in use, said exterior of said cannula being configured to securely fit into said disc opening.

63. (previously presented) The device of claim 62, wherein said seal includes a sealing element disposed in said lumen.

64. (previously presented) The device of claim 63, wherein said sealing element comprises an elastomeric ring support in said lumen and configured for fluid-tight engagement with said tube.

65. (previously presented) The device of claim 55 further including a vent extending through said cannula for communicating with said disc space.

66. (previously presented) A device for sealably introducing fluent material directly into the disc space through an opening formed through the annulus fibrosis of said disc, comprising:

a generally elongate cannula having a proximal end and an opposing distal and lumen extending therethrough for the receipt and passage of fluent material, said distal end being configured for entry into said opening in said annulus fibrosis; and

a seal on said cannula at said distal end thereof, said seal being configured for sealably engaging the surface of said annulus fibrosis defined by said opening to provide a seal thereat.

67. (previously presented) The device of claim 66, wherein said seal is integral with at least a portion of said cannula.

68. (previously presented) The device of claim 66, wherein said seal is a separate component disposed on said cannula.

69. (previously presented) The device of claim 66, wherein said distal end of said cannula is defined by an insertion tip configured for facilitating entry into said opening.

70. (previously presented) The device of claim 69, wherein said insertion tip is separable from said cannula.

71. (previously presented) The device of claim 70, wherein said seal is disposed on said insertion tip.

72. (previously presented) The device of claim 69, wherein said insertion tip is configured to engage end plates of opposing vertebrae upon insertion into said opening and to distract said vertebrae.

73. (previously added) A device for distracting two adjacent vertebral bodies defining a disc space therebetween and for delivering a flowable material into the disc space, comprising a body including a proximal portion, an opposite distal portion defining a shape adapted to distract the disc space, and a first longitudinal passageway extending through the body and defining a first opening in the distal portion opening into the disc space.

74. (previously added) The device of claim 73 wherein:  
the passageway further defines an injection port in the proximal portion of the body; and  
the device further comprises an injection device having a port attached to the injection port.

75. (previously added) The device of claim 74 wherein the injection device is a syringe.

76. (previously added) The device of claim 73 wherein the shape adapted to distract is adapted to distract upon insertion into the disc space.

77. (previously added) The device of claim 76 wherein the shape adapted to distract has a width and a height, wherein the width is greater than the height

78. (previously added) The device of claim 76 wherein the shape adapted to distract is adapted to distract upon insertion into the disc space and then rotation in the disc space.

79. (previously added)      The device of claim 73 wherein the shape adapted to distract is removable.

80. (previously added)      The device of claim 73 further comprising a stop means extending radially from a longitudinal axis of the proximal portion of the body.

81. (previously added)      The device of claim 73 wherein the shape adapted to distract has an upper bearing surface and a lower bearing surface, and wherein the upper and lower surfaces define a non-zero angle.

82. (previously added)      The device of claim 73 further comprising a tube having an open distal end adapted for insertion in the injection port.

83. (previously added)      The device of claim 73 wherein the body further includes a second longitudinal passageway extending through the body and defining a second opening in the distal portion opening into the disc space.

84. (previously added)      The device of claim 73 wherein the first opening into the disc space is located within a distal half of the shape adapted to distract.

85. (previously added)      The device of claim 73 wherein the first opening into the disc space is located within a distal quarter of the shape adapted to distract.

86. (previously added)      The device of claim 73 wherein the first opening into the disc space is located at the distal end of the shape adapted to distractor.

87. (previously added)      A method for distracting two vertebral bodies and delivering a flowable material into an intervertebral disc space having an outer annulus, comprising the steps of:

    a) providing a device for distracting and delivering a flowable material comprising, a body having a proximal portion and a distal portion, the distal portion

defining a shape adapted to distract, the body also having a longitudinal passageway defining a first opening in the distal portion, and a first injection port in the proximal portion;

- b) inserting the distal portion of the device through the outer annulus;
- c) distracting the vertebral bodies with the shape; and
- d) introducing the flowable material into the disc space through the injection port.

88. (previously added)      The method of claim 87 further comprising the step of:

- e) removing the device after step d).

89. (previously added)      The method of claim 87 wherein the shape is adapted to distract upon insertion and the distraction step is accomplished by advancing the device into the disc space.

90. (previously added)      The method of claim 87 wherein the shape is a spreader and the distraction step is accomplished by rotating the device.

91. (previously added)      The method of claim 87 wherein the step of inserting is accomplished through a single incision in the outer annulus.

92. (previously added)      A kit for providing a nucleus pulposus replacement material, comprising:

a) device for distracting two adjacent vertebral bodies defining a disc space therebetween and delivering a flowable material into the disc space including a body having;

- i) a proximal portion;
- ii) a distal portion comprising a shape adapted to distract the disc space;

and

iii) a longitudinal passageway extending through the body and defining a first opening in the distal portion opening into the disc space; and



b) a flowable material suitable for use as a nucleus pulposus replacement material.

93. (previously added)      A device for distracting two adjacent vertebral bodies defining a disc space therebetween and delivering a flowable material into the disc space, comprising:

means for distracting the disc space, and

means for delivering a flowable material into the disc space.

94. (new)      A method of restoring disc height between two opposing vertebral bodies of the spine, comprising the steps of:

creating an opening through the disc annulus fibrosus in communication with the intradiscal space;

distracting the vertebral bodies apart to a selected spacing approximating the natural disc height;

sealing the opening created in said annulus fibrosus;

introducing a curable biomaterial through said sealed opening directly into the intradiscal space until the intradiscal space is substantially filled; and

allowing the biomaterial to be substantially cured *in situ*.

95. (new)      The method of claim 94, wherein the step of sealably introducing the curable biomaterial includes introducing the biomaterial under pressure.

96. (new)      The method of claim 95, wherein said pressure is substantially maintained until the biomaterial is cured.

97. (new)      The method of claim 94, wherein the distraction step is performed prior to the step of introducing the curable biomaterial.

98. (new)      The method of claim 94, wherein the distraction is maintained until the biomaterial is substantially cured.

99. (new) The method of claim 94, wherein the distraction step is performed by a separate distractor.

100. (new) The method of claim 99, wherein said distractor is a cannulated distractor having a lumen in communication with the intradiscal space.